K133633

4. 510(k) Summary

JUN 0 2 2014

Submitter's Name / Contact Person

Submitter:	TriReme Medical, LLC 7060 Koll Center Parkway, Suite 300 Pleasanton, CA 94566 U.S.A.
Contact Person:	Shiva Ardakani VP of Regulatory / Quality Phone: (925) 931-1300 Fax: (925) 931-1361

Date Prepared: November 25, 2013

General Information

Trade Name:	Chocolate™ PTCA Balloon Catheter
Common / Usual Name:	PTCA catheter
Product Code:	LOX
Classification Name:	Percutaneous transluminal coronary angioplasty (PTCA) catheter [21 CFR 870.5100(a)]
Predicate Device:	Glider PTCA Balloon Catheter (TriReme Medical) – (K111544 and K121681)

Device Description

The Chocolate PTCA Balloon Catheter is a Rapid Exchange (RX) angioplasty balloon catheter. It consists of a stainless steel hypotube and a nylon shaft, a semi compliant balloon at the distal end of the catheter with a metal constraining structure (CS) and an atraumatic distal tip. Upon inflation, the CS expands with the balloon to a certain diameter; the balloon continues the expansion beyond the CS. Upon deflation, the CS returns to its original shape, and is removed from the vessel along with the balloon catheter. Two Radiopaque markers are added to define the working length of the Chocolate Balloon. The proximal end of the catheter is comprised of a hub used to inflate the balloon that can be connected to a standard inflation device. The catheter will be 140 ±5cm in length, compatible with 0.014" guidewire.

Intended Use / Indications

The Chocolate™ PTCA Balloon Catheter is indicated for balloon dilatation of the stenotic portion of coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

Technological Characteristics/Performance Testing/Substantial Equivalence

The subject device is substantially equivalent in technological characteristics to the predicate device. Although the presence of the CS structure on Chocolate PTCA balloon is unique to the subject device; this design feature is intended to make the balloon inflation more uniform and the deflation of the balloon more rapid. Addition of the CS structure does not alter the safety or effectiveness profiles of the Chocolate PTCA Balloon Catheter (subject) compared to the Glider PTCA Balloon Catheter (predicate).

The subject device has classification information, indication for use, fundamental design features, mechanism of action, materials, and principle of operation identical to the predicate device. The device specifications are all similar and within the range of the predicate devices. Testing requirements for this device was based upon the *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (September 8, 2010).*

- Dimensional Verification
- Balloon Preparation, Deployment & Retraction
- Flexibility & Kink
- Balloon Rated Burst Pressure (RBP)
- Balloon Fatigue
- Balloon Compliance
- Balloon Inflation and Deflation
- Catheter Bond Strength
- Tip Pull Test
- Torque Strength
- Radiopacity
- Particulate Evaluation
- Biocompatibility Testing

No new questions of safety or effectiveness were identified during device testing; therefore, the Chocolate PTCA Balloon Catheter is considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 2, 2014

TreReme Medical, LLC
c/o Ms. Shiva Ardakani
7060 Koll Center Parkway
Suite 300
Pleasanton, CA 94566

Re: K133633
Device Name: Chocolate PTCA Balloon Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: May 9, 2014
Received: May 12, 2014

Dear Ms. Ardakani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indications for Use

510(k) Number (XXXXX): K133633

Device Name: Chocolate™ PTCA Balloon Catheter

Indications for Use:

The Chocolate™ PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)